

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

**IN RE: ETHICON, INC.,  
PELVIC REPAIR SYSTEM  
PRODUCTS LIABILITY LITIGATION**

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**MDL NO. 2327**

**THIS DOCUMENT RELATES TO:  
ETHICON WAVE CASES LISTED  
IN EXHIBIT A**

**JOSEPH R. GOODWIN  
U.S. DISTRICT JUDGE**

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE  
CERTAIN GENERAL OPINIONS OF E. STANTON SHOEMAKER, M.D.**

Plaintiffs submit this brief in support of their motion to exclude certain general opinions of Stanton Shoemaker, M.D. as it relates to the cases set forth in Exhibit A to Plaintiff's accompanying motion.

**INTRODUCTION**

E. Stanton Shoemaker, M.D. ("Dr. Shoemaker") is a board certified obstetrician-gynecologist licensed in the state of Texas with experience in the treatment of stress urinary incontinence ("SUI") and pelvic organ prolapse ("POP").<sup>1</sup> Dr. Shoemaker intends to provide general opinions about TVT and TVT-O (collectively "the TVT Devices"), used to treat SUI, as well as Gynemesh PS, Prolift, Prolift +M, and Prosima (collectively "the POP Devices"), and used to treat POP.<sup>2</sup> As set forth below, the Court should preclude Dr. Shoemaker from testifying about matters that are beyond his expertise, that are unreliable, that are irrelevant, and/or otherwise improper.

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<sup>1</sup> Ex. B.

<sup>2</sup> See generally Ex. C and D.

### **LEGAL STANDARD**

The admissibility of expert opinion testimony is governed by the Federal Rules of Evidence. *Daubert v. Merrell Dow Pharms.* 509 U.S. 579, 587 (1993). In a federal court sitting in diversity jurisdiction, the admissibility of expert testimony is a question of and controlled by federal law. *See, e.g., Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (quoting *Scott v. Sears, Roebuck & Co.*, 789 F.2d 1052, 1054 (4th Cir. 1986)); *Fraley v. Stoddard, D.P.M.*, 73 F. Supp. 2d 642, 646 (S.D. W. Va. 1999). In multidistrict litigation, the law of the transferee circuit governs questions of federal law. *See, e.g., In re Temporomandibular Joint Implants Prod. Liab. Litig.*, 97 F.3d 1050, 1155 (8th Cir. 1996) (citation omitted), *aff'd*, 490 U.S. 122 (1989); *In re Stucco Litig.*, 364 F. Supp. 2d 539, 540 (E.D.N.C. 2005) (“[i]n the context of this multidistrict case, the court must apply the law of the Fourth Circuit when analyzing questions of federal law.”).

In accordance with these rules, the trial judge serves as a gatekeeper to the admission of scientific testimony. *See id.* at 589. This gatekeeping function applies not only to “scientific” testimony, but also to testimony based on “technical” and “other specialized” knowledge. *Kumho Tire Co., Ltd., v. Carmichael*, 526 U.S. 137, 141 (1999). The proponent of opinion testimony bears the burden of establishing its admissibility. *See, e.g., Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001). Where, as here, the proponent fails to establish all prerequisites to admissibility under Rule 702 exclusion of expert testimony is within the trial court’s sound discretion. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142, (1997); *see also Cooper*, 259 F.3d at 200. Nevertheless, the court “may not abdicate its responsibility to ensure that only properly admitted evidence is considered by the jury. Expert evidence based on assumptions not supported by the record should be excluded.” *Tyger Const. Co., Inc. v. Pensacola Const. Co.*, 29

F.3d 137, 144 (4th Cir. 1994) (district court abused its discretion by admitting expert testimony due to the absence of factual support and the speculative nature of the underlying calculations).

### **ARGUMENT**

Dr. Shoemaker's medical training in the field of obstetrics and gynecology does not automatically render his opinions on other ancillary issues admissible. *See Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 (10<sup>th</sup> Cir. 2001). Indeed, each individual opinion he offers must satisfy the requirements of the Federal Rules of Evidence to be admissible. *See e.g., Gen. Elec. Co.*, 522 U.S. at 142; *see also Daubert*, 509 U.S. at 579.

As a threshold matter, an expert witness "must have 'knowledge, skill, experience, training, or education' in the subject area in which he will testify." *Bombardiere v. Schlumberger Tech. Corp.*, 934 F. Supp. 2d 843, 846 (N.D. W. Va. 2013) (quoting Fed. R. Evid. 702). In the context of Rule 702, knowledge "connotes more than subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590. Trial courts must ensure that a purported expert witness "is not merely parroting the opinions of others, but that the *matters upon which she will opine are clearly within her area of expertise*." *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 722, 730 (E.D.N.C. 2007) (emphasis added). One of the most fundamental prerequisites to admission of an expert's opinion is that the opinion be related to that expert's specialized knowledge. *See, e.g., U.S. v. Johnson*, 54 F.3d 1150, 1157 (4th Cir. 1995). Under this clear standard, Dr. Shoemaker, just like any other expert witness, may only testify on subjects within his expertise.

Additionally, Dr. Shoemaker's opinions must be based upon reliable and proper methods as well as within his field of expertise. *See Coleman v. Union Carbide Corp.*, 2013 U.S. Dist. LEXIS 140613, \* 50 (S.D. W. Va. 2013) (holding that expert testimony must be reliable and relevant to be admissible). As this Court has recognized in this litigation:

Just because an expert may be “qualified . . . by knowledge, skill, experience, training or education” does not necessarily mean that the opinion that the expert offers is “the product of reliable principles and methods” or that the expert “has reliably applied the principles and methods to the facts of the case.”

*Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013). The burden is on the Defendant to show that *each* of Dr. Shoemaker’s opinions has a reliable foundation based on stated principles and methods. *See Daubert*, 509 U.S. at 597. Opinions which are not within Dr. Shoemaker’s area of expertise and which are not the product of reliable principles and methods should be excluded.

**I. DR. SHOEMAKER’S OPINIONS REGARDING THE STATE OF MIND OR KNOWLEDGE OF OTHER DOCTORS ARE UNRELIABLE AND SHOULD BE EXCLUDED.**

In his report, Dr. Shoemaker repeatedly opines that certain complications are well known to “all” physicians, and that he is qualified to opine on what information “all” physicians rely upon and what risks “all” physicians are aware of. Dr. Shoemaker states that no doctor relies on the IFU, and that many surgeons do not even read the IFU.<sup>3</sup> Dr. Shoemaker then goes on to state that “we” do not have time to meet with manufacturers, and “we” do not expect them to provide us with risk information, rather “we” rely on published literature.<sup>4</sup> Dr. Shoemaker has no basis for opining on what any physician besides himself reads or relies upon for risk information.

Dr. Shoemaker also opines that even though the IFU does not contain all the known risks, that “any surgeon practicing pelvic reconstructive surgery understands that these complications may cause pain and dyspareunia, as well as the need for additional surgery.”<sup>5</sup> Dr. Shoemaker cites no basis for how he determined this. Dr. Shoemaker’s opinions regarding the state of mind or knowledge of “all physicians” is improper and should be excluded.

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<sup>3</sup> Ex. C at 35.

<sup>4</sup> *Id.*

<sup>5</sup> Ex. C at 36.

## II. DR. SHOEMAKER OPINIONS REGARDING THE ADEQUACY OF ETHICON IFUS SHOULD BE EXCLUDED.

In his reports, Dr. Shoemaker opines that Ethicon's IFUs adequately warned of all potential risks for all the TVT devices<sup>6</sup> and POP devices.<sup>7</sup> However, Dr. Shoemaker has absolutely no experience drafting an IFU<sup>8</sup> nor knowledge of the requirements necessary to be included in an IFU.<sup>9</sup>

This Court has previously recognized that a doctor who is unfamiliar with federal regulations regarding IFUs is unqualified to testify about the adequacy of warnings. *See, Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013). Training and experience as a doctor does not qualify a witness as an expert on the adequacy of product warnings. *See In re: Diet Drugs Prod. Liab. Litig.*, 2001 U.S. Dist. LEXIS 1174, \* 27-28 (E.D. Pa. 2001). Because Dr. Shoemaker lacks the knowledge, skill, experience, training, and education needed to provide an expert opinion on the adequacy of warnings in a medical device IFU, his testimony and opinions concerning the warnings in the IFU are inadmissible under *Daubert*.

Even if Dr. Shoemaker were qualified to testify as to the adequacy of the warnings, contraindications and adverse events outlined in the IFU (which he is not), his opinions remain inadmissible because they are not the product of a reliable methodology. Dr. Shoemaker's Expert Reports merely assert the adequacy of the IFU without explaining the reasoning or methodology behind his opinions.

Dr. Shoemaker's reports state "it is my opinion that Ethicon adequately apprised physicians practicing pelvic reconstruction surgery of the risk associated with the use of TVT

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<sup>6</sup> Ex. D at 31.

<sup>7</sup> Ex. C at 36

<sup>8</sup> *See generally*, Ex. B.

<sup>9</sup> Ex. E at 130:20-132:3.

and POP devices and that risk associated with these products were adequately described in their respective IFUs and other professional material.”<sup>10</sup> Dr. Shoemaker provides no support for his contention that these general warnings are sufficient under federal law. These baseless assertions fail to provide the necessary foundation under *Daubert*. This lack of foundation is further grounds for excluding Dr. Shoemaker’s opinions on the adequacy of Ethicon’s IFUs. As such, Dr. Shoemaker is not qualified to testify regarding any of Ethicon’s IFUs and his opinions are unreliable.

### **III. DR. SHOEMAKER’S OPINIONS REGARDING THE PHYSICAL PROPERTIES OF POLYPROPYLENE, SPECIFICALLY DEGRADING, PARTICLE LOSS, ROPING, FRAYING, CURLING, AND CYTOTOXICITY SHOULD BE EXCLUDED.**

In his report, Dr. Shoemaker states that the Plaintiffs claim that polypropylene mesh is carcinogenic, degrades in situ, contracts, and results in particle loss are litigation driven with no accepted or reliable clinical data.<sup>11</sup> Dr. Shoemaker also opines that if there were in fact reliable data suggesting that polypropylene mesh caused permanent malady through particle loss, degradation, roping, fraying, and curling, organizations like the American Urogynecologic Society, American Urologic Association, International Urogynecologic Association, and American College of Obstetricians and Gynecologists would not recommend them.<sup>12</sup> Dr. Shoemaker should be prohibited from testifying as to these opinions in front of the jury because, 1) Dr. Shoemaker is unqualified to give these opinions and, 2) Dr. Shoemaker has provided no basis for these opinions.

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<sup>10</sup> Ex. C at 36.

<sup>11</sup> See *id.* at 32-33; See Ex. D at 21-22.

<sup>12</sup> See Ex C. at 32-33.

Dr. Shoemaker admits that he is not a pathologist.<sup>13</sup> He admits that he is not a biomaterials expert.<sup>14</sup> Dr. Shoemaker has no specialized knowledge, skill, experience, training, or education in pathology other than his general training as a medical professional.<sup>15</sup> Nonetheless Dr. Shoemaker expresses “expert” opinions related to the pathological findings of explanted mesh that he has not examined.<sup>16</sup> For example, Dr. Shoemaker testified during his deposition that, 1) mesh does not shrink in the human body<sup>17</sup> (a mesh characteristic even Ethicon acknowledges)<sup>18</sup>, and 2) if mesh does shrink, there is no clinical significance of the mesh shrinkage.<sup>19</sup> By his own admission, Dr. Shoemaker has never microscopically examined explanted mesh.<sup>20</sup> He has therefore never measured whether the shape or size of the mesh has changed, which would or would not indicate shrinkage. Also, because he has also never microscopically examined explanted mesh or tested it in any way, he is unable to determine whether or not the mesh has or has not degraded. Dr. Shoemaker is neither a biomaterials expert nor a pathologist, thus he is not qualified to opine generally about the physical properties of polypropylene and how it reacts in the human body. Therefore each of Dr. Shoemaker’s opinions regarding mesh degradation, particle loss, roping, fraying, curling, and cytotoxicity are unreliable and should be excluded because he fails to provide a sound basis for his opinions.

Dr. Shoemaker’s opinions regarding the pathological findings of explanted mesh should be excluded because they are outside the scope of Dr. Shoemaker’s area of expertise as a practicing ob-gyn. Dr. Shoemaker simply does not have the requisite experience, training, or

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<sup>13</sup>Ex D, at 151:8-10.

<sup>14</sup>*Id.* at 151:13-16.

<sup>15</sup>*See generally*, Ex. B.

<sup>16</sup>*See id.* at 54:11-20.

<sup>17</sup>*See id.* 78:19-21.

<sup>18</sup>*See* Ex. F.

<sup>19</sup>*See id.* at 83:23-84:2.

<sup>20</sup>*See id.* at 54:11-20

education to proffer these opinions, nor has he utilized *any* method – let alone a reliable method – to reach the conclusions outlined in his report. Dr. Shoemaker’s opinions amount to nothing more than baseless assumptions and the law is clear that such “unsupported speculation” is not only insufficient, but precisely what *Daubert* aims to prevent. *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, \*3 (4th Cir., Sept. 8, 1997) (the expert’s testimony must be grounded in methods and procedures in science and not subjective belief or unsupported speculation).

#### **IV. DR. SHOEMAKER’S LEGAL CONCLUSIONS SHOULD BE EXCLUDED.**

Dr. Shoemaker improperly offers legal conclusions under the guise of expert testimony. For example in his reports, Dr. Shoemaker states:

- Gynemesh PS is not defective.<sup>21</sup>
- Ethicon adequately warned physicians of the risk associated with the use of Gynemesh PS, Prolift, Prosima and Prolift +M and that the risks associated with these products were adequately described in their respective IFUs and other professional materials.<sup>22</sup>
- Ethicon adequately warned physicians of the risks associated with the use of the TVT line of products, and that risk associated with these products were adequately described in their respective IFSs and other professional material.<sup>23</sup>
- Professional education offered by Ethicon has been more than adequate.<sup>24</sup>
- Ethicon was very responsible and thorough in the way they studied their products and trained physicians.<sup>25</sup>

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<sup>21</sup> *Id.* at 17.

<sup>22</sup> *Id.* at 36.

<sup>23</sup> Ex. D at 31

<sup>24</sup> Ex. C at 37; Ex. D at 32.

<sup>25</sup> *Id.*

The determination regarding the adequacy of warnings, adequacy of training, adequacy of post market surveillance, and product design are beyond his scope of expertise and issues for the jury. This Court has correctly and repeatedly held that legal conclusions are improper subject of expert testimony. Dr. Shoemaker's opinions regarding legal conclusions should be excluded.

### **CONCLUSION**

For the reasons above, this Court should grant Plaintiff's Motion to Limit the Opinions and Testimony of Stanton Shoemaker, M.D.

Dated: April 26, 2016

Respectfully submitted,

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**ATTORNEYS FOR PLAINTIFFS**

**CERTIFICATE OF SERVICE**

I hereby certify that on April 26, 2016, a true and correct copy of Plaintiffs' Memorandum in Support of Their Motion to Limit the Opinions and Testimony of Stanton Shoemaker, M.D. was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

Dated: April 26, 2016

Respectfully submitted,

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